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10/587,728

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EXAMINER

ROYSTON, ELIZABETH

ART UNIT

PAPER NUMBER

1791

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DELIVERY MODE

12/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/587,728 | Applicant(s) ROTHBRUST ET AL. | |
| | Examiner Elizabeth Royston | Art Unit 1791 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment to claims 1, 3, 12, 17, 19, and 20 in the response dated 8/24/2009 is noted and accepted.

2. Claims 1-24 as amended on 8/24/2009 are examined in the instant Official Action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 4, 5, 8-15, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glass (US PN 5478785) in view of Jones (US PGPub 2002/0197583).

Art Unit: 1791

With regard to claim 1, Glass teaches a process for producing an inorganic-inorganic composite material in which after shape-imparting processing (col. 7, line 15-17; figure 1) and pre-sintering (col. 7, line 20-21) of a powder containing an oxide ceramic, an open-pore, crystalline oxide ceramic is created (col. 7, line 21-23). The ceramic shape is then infiltrated with a hydrolysable silane precursor (col. 7, line 31-33) at room temperature (col. 4, line 45-47) followed by sintering to a density of at least -- 99.5% (col. 4, line 59) at a temperature from 1000-1600°C (col. 7, line 37-38, 40, 45-49) in air (col. 6, line 46; col. 7, line 38). Although Glass does not explicitly state sintering at ambient pressure, Glass teaches the sintering process occurs in air (col. 6, line 46; col. 7, line 38), indicating atmospheric conditions. Furthermore, Glass does not make any mention to a vacuum or other pressure affecting device, or provision for a change in pressure during sintering. Therefore, since the use of a vacuum or other pressure affecting device would require the increased complexity of the system in addition to adding considerable cost, the Examiner interprets the teaching of Glass to be at ambient pressure.

Glass does not explicitly teach an infiltration time of less than 10 minutes; however, Glass does show a direct relationship between desired infiltration depth and infiltration time (col. 5, line 9), which establishes the infiltration time as a result effective variable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the instantly claimed ranges through process optimization, since it has been held that there the general conditions of a claim are

Art Unit: 1791

disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See *In re Boesch*, 205 USPQ 215.

Glass does not explicitly teach the material as having a retentive pattern or being acid etched.

Jones teaches that it was known in the art at the time of the invention to use HF acid to etch the surface of ceramic material to form retentive patterns (paragraph 19, line 1-4; paragraph 30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the acid etching to form a retentive pattern on the ceramic material in the teaching of Glass. The rationale to do so would have been the motivation provided by the teaching of Jones, that to use such an acid etching technique predictably results in the formation of retentive patterns on the surface which prepares the ceramic surface for further bonding with additional materials (paragraph 30, line 1-2, 6).

With regard to claim 4, Glass teaches pre-sintering at 600 to 1300°C (col. 7, line 20, 25-26).

With regard to claim 5, Glass teaches an optional in vacuo infiltration (col. 3, line 49).

With regard to claims 8, 11-12, although Glass does not specifically teach an infiltration layer thickness of 10 to 90% of the pre-sintered open-pore crystalline oxide

Art Unit: 1791

ceramic thickness, Glass teaches that the infiltrate layer thickness is dependent only on time (assuming consistent pore size in the pre-sintered ceramic and viscosity of the infiltrate), in a known relationship (col. 5, line 9). Therefore, the layer thickness of the infiltrate relative to the thickness of the preform is dependent only on the initial size of the preform and the calculated time of infiltration. It would have been obvious to one of ordinary skill in the art to adjust the time of infiltration so that the layer thickness was between 10 to 90% of the thickness of the pre-sintered open-pore crystalline oxide ceramic.

With regard to claims 9 and 10, although Glass does not specifically teach an infiltration layer thickness between 5 and 20% of the sintered composite material, Glass does teach shrinking of the composite upon sintering (col. 5, line 34-39). It would have been obvious to one of ordinary skill in the art at the time of the invention that if the infiltrated preform of claim 8 was sintered in the same environment as the instant claim 1, then the final sintered composite would have an infiltrate layer thickness from 5 to 20% of the sintered composite material.

With regard to claims 13-15, Glass teaches a polar water solvent (col. 7, line 31-33).

Art Unit: 1791

With regard to claim 22, Glass teaches shape-imparting processing into the “required size and shape” (col. 7, line 15-17), including monolithic blocks (the porous alumina preform in the upper left corner of figure 1).

6. Claims 2, 3, 16, 17, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glass (US PN 5478785) in view of Jones (US PGPub 20020197583 A1), as applied for claims 1, 4, 5, 8-15, and 22 above, and further in view of Tyszblat (US PN 5447967).

With regard to claims 2 and 3, Glass in view of Jones does not specifically disclose the use of an organic binder.

Tyszblat teaches several possible organic binders in the oxide ceramic powder, including cellulose (col. 2, line 24-33).

It would have been obvious to one of ordinary skill in the art to use the binder taught by Tyszblat in the ceramic taught by Glass in view of Jones. The rationale to do so would have been provided by the motivation found in the teaching of Tyszblat, that to use an organic binder predictably provides a means to fix the shape of the shaped ceramic perform (col. 1, line 41-44).

With regard to claims 16 and 17, Glass in view of Jones does not specifically disclose machining prior to infiltration or after sintering.

Tyszblat teaches machining prior to infiltration (col. 3, line 42-43) and post infiltration/sintering (col. 3, line 59-60). Although explicit mention of the pressure when

Art Unit: 1791

machining the product (col. 5, line 13-16) is not made by Tyszblat, the applied vacuum is only discussed when the product is held at higher temperatures (col. 3, line 49-52). Once the product cooled it would have been obvious to one of ordinary skill in the art at the time of the invention to remove the product from the vacuum and to perform any subsequent machining/polishing at atmospheric pressure, as to do otherwise would generate additional complexity in the process.

It would have been obvious to one of ordinary skill in the art at the time of the invention to machine the ceramic prior to infiltration and after infiltration. The rationale to do so would have been provided by the motivation found in the teaching of Tyszblat, that to shape the un-infiltrated ceramic predictably enables a better control over the final shape of the ceramic, for example the fit of an artificial tooth (col. 2, line 65-68; col. 3, line 11-13), and to shape after sintering predictably allows for the removal of excess material (col. 3, line 59-60).

With regard to claims 20 and 21, Glass in view of Jones does not explicitly disclose an oversize of 15 - 30%.

Tyszblat teaches the removal of material to shape the perform to the desired configuration (col. 3, line 42-43; col. 3, line 59-60).

Tyszblat does not explicitly disclose a specific oversize for the product at any step; however, it would have been obvious to one of ordinary skill in the art at the time of the invention to include sufficient oversize in the initial preform optimized such that

Art Unit: 1791

the desired final shape and size of the product can be achieved through machining by removing product (i.e. sandblasting col. 5, line 13).

7. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glass (US PN 5478785) in view of Jones (US PGPub 20020197583 A1), as applied for claims 1, 4, 5, 8-15, and 22 above, and further in view of Kondo (US PN 4626392).

With regard to claims 18 and 19, Glass in view of Jones does not explicitly disclose attaching at least a one-layer coating of a further material to the surface of the composite material or subjecting the layered composite and further material to heat treatment.

Kondo teaches attaching an additional layer of a further material to the surface of the composite material and subjecting the layered composite and further material to heat treatment (col. 3, line 55-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the additional layers taught by Kondo to the process for making a composite material taught by Glass in view of Jones. The rationale to do so is the motivation provided by the teaching of Kondo, that to include the layer of a further material predictably produces ceramic materials suitable for surgical implantation (col. 3, line 50-53).

Art Unit: 1791

8. Claims 23 and 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Glass (US PN 5478785) in view of Jones (US PGPub 20020197583 A1), as applied for claims 1, 4, 5, 8-15, and 22 above, and further in view of Tyszblat (US PN 5447967) and Franek (US PN 4830655).

With regard to claims 23 and 24, although Glass in view of Jones does teach infiltration under vacuum (Glass, col. 3, line 49), Glass in view of Jones does not specifically disclose chip-forming machining of the monolithic block before applying the infiltration substance under vacuum.

Tyszblat teaches applying the infiltration substance in vacuo (col. 3, line 50-52) after shaping with machining (col. 3, line 42-43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the vacuum infiltration after shaping taught by Tyszblat in the process taught by Glass in view of Jones. The rationale to do so would have been found in the motivation provided by the teaching of Tyszblat, that to that to shape the un-infiltrated ceramic predictably enables a better control over the final shape of the ceramic, for example the fit of an artificial tooth (col. 2, line 65-68; col. 3, line 11-13), and that to infiltrate under vacuum predictably results in the successful infiltration of a porous material with glass (col. 3, line 44-52).

Glass in view of Jones and Tyszblat does not explicitly disclose chip-forming machining.

Franek teaches chip-forming machining for the cutting of Al and Zr oxide materials (col. 4-5, line 66-68, 1-3).

Art Unit: 1791

It would have been obvious to one skilled in the art at the time of the invention to use of the chip-forming machining taught by Franek in the machining step taught by Glass in view of Jones and Tyszblat. The rationale to do so would have been the motivation provided by the teaching of Franek, that to use such machining and polishing techniques will predictably give fine surfaces on Al and Zr oxides (col. 1, line 46-49).

Response to Arguments

9. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's arguments filed 8/24/2009 have been fully considered but they are not persuasive.

With regard to Applicant's argument that Glass does not deal with a material for use in the dental field and thus is not a suitable reference, the Examiner respectfully disagrees. The limitation "for use in the dental field" is a use limitation and fails to provide functional limitations with regard to the method of making an inorganic-inorganic composite material.

Furthermore, Glass deals with a material designed to be tailored for specific situations (col. 1, line 12-18), including increasing the hardness (col. 2, line 18-21) and strength (col. 1, line 50-52) of the material: nowhere in the teaching of Glass is there an indication that the material can not be used in the dental field. Since the limitation "for use in the dental sector" has been considered as a statement of intended use, it is the

Art Unit: 1791

Examiner's position that the material taught by Glass is capable of performing the intended use, as further evidenced by Leonhardt (WO99/52467), and therefore meets the limitations of the claim.

Finally, with regard to Applicant's argument that the hardness of the material in Example 1 of the teaching of Glass covers the range from 723 MPa to 837 MPa and thus is less than 800 MPa is a possible misinterpretation by Applicant of the teaching of Glass. The purpose of the invention in the teaching of Glass is partly to demonstrate that the strength of the ceramic composite material can be increased through the addition of aluminum oxide (col. 1, line 16-17). Therefore, the Examiner interprets the strength of 837 MPa as the final strength of the material in the teaching of Glass with 4-5 v% aluminum oxide content, increased from the strength of the comparative example of 723 MPa without an aluminum oxide content (col. 7, line 1-3), as can be seen from the quote "Mechanical property measurements have shown the addition of aluminum oxide in the range of 4 to 5% (volume) increased the bend strength from 723 to 837 MPa...". However, if the Examiner's initial interpretation is incorrect, and instead the range of 723 MPa to 837 MPa represents the increase in strength due to increasing the aluminum oxide content from 4 v% to 5 v%, the case of 5 v% of aluminum oxide in the ceramic material in the teaching of Glass still represents a material with a strength of no less than 800 MPa.

With regard to Applicant's assertion that there would be no reason to combine the teaching of Tyszblat with the teaching of Glass, the Examiner respectfully disagrees.

Art Unit: 1791

The teaching of Tyszblat is relied upon for teaching known methods of infiltrating substances into porous ceramic materials combined with shaping of the infiltrated and sintered ceramic materials, and for teaching the concept of a cellulose binder material. The concept of aiding the infiltration of a porous material with a vacuum is not dependent upon the temperature of infiltration or composition of the porous material or infiltrate, since a vacuum will result in an applied force regardless of the temperature or materials used. Similarly, the concept of shaping or machining a sintered ceramic material does not change with the composition of the sintered ceramic. The order of steps in the teaching of Tyszblat would have been obvious to one of ordinary skill in the art at the time as stated on page 9, line 9-14 in the previous Official Action dated 5/21/2009, since to shape the un-infiltrated ceramic predictably enables a better control over the final shape of the ceramic, for example the fit of an artificial tooth (col. 2, line 65-68; col. 3, line 11-13), and to shape after sintering predictably allows for the removal of excess material (col. 3, line 59-60). Finally, as described on page 8, line 13-14 in the previous Official Action dated 5/21/2009, Tyszblat teaches the concept of using a cellulosic binder material for binding together oxide ceramic materials, the limitation of the claim, and further teaches that it would have been obvious to one of ordinary skill in the art at the time of the invention to use a cellulosic binder since to use an organic binder predictably provides a means to fix the shape of the shaped ceramic perform (col. 1, line 41-44). However, even if the limitation were amended to include or exclude specific oxide materials, the inclusion of a cellulosic material in a preform comprising

Art Unit: 1791

ceramic oxide materials is well known, including those ceramic oxide materials described by Applicant (Leonhardt WO 99/52467, page 5, line 6, 11-14).

Applicant's argument that no oxide ceramics are used in the teaching of Tyszblat does not appear to agree with the teaching of Tyszblat, where spinel is an porous oxide ceramic (MgAl_2O_4), as evidence by Laobuthee et al., *J. Eur. Ceram. Soc.* 2000, **20**, 91-97 (abstract, line 1; page 91, col. 2, paragraph 2, line 1; page 92, col. 1, paragraph 2, line 2, paragraph 3, line 1-3; page 92, col. 2, section 3, paragraph 1, line 1), and alumina (Al_2O_3), magnesia (MgO), silica (SiO_2), and mullite ($3\text{Al}_2\text{O}_3\text{-}2\text{SiO}_2$) are all common names for known oxide ceramics (col. 3, line 14-17). Additionally, Tyszblat teaches that up to 30 wt% of the composition includes the alumina (Al_2O_3), magnesia (MgO), silica (SiO_2), or mullite ($3\text{Al}_2\text{O}_3\text{-}2\text{SiO}_2$) materials (col. 3, line 15), rather than the exclusive use of the spinel oxide material asserted by Applicant on page 16, line 2-3 of the response dated 8/24/2009.

With regard to Applicant's argument that the structure of the material in the teaching of Tyszblat is different than the structure of the material as claimed by Applicant, while the Examiner agrees that the aluminum oxide material specifically described by Applicant as the primary oxide component is different than the primary spinel oxide ceramic component in the teaching of Tyszblat, nowhere in the claims 1-24 is a limitation recited that excludes the spinel oxide ceramic material as the primary oxide component or claims that only ceramic oxides with a specific molecular structure can function as the primary ceramic oxide component.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Royston whose telephone number is 571-270-7654. The examiner can normally be reached on M-Th 8:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1791

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ER/

Patent Examiner, GAU 1791

/Christina Johnson/

Supervisory Patent Examiner, Art Unit 1791